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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,506	BAST ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *2,10 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15 January 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for examination.

Acknowledgement of the present application as a continuation of U.S. Patent Application No. 10/323,101 filed December 18, 2002, now abandoned, which is a continuation of U.S. Patent Application No. 09/577,732 filed May 23, 2000, now abandoned, which claims priority under 35 U.S.C. 119(e) to United States Provisional Application No. 60/141,487 filed June 29, 1999. Applicant's Preliminary Amendment filed January 15, 2004 has been received and entered into the application. Accordingly, the specification at pages 1 and 4-5 has been amended. Applicant's Information Disclosure Statement (IDS) filed January 15, 2004 has also been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (seven pages total), the Examiner has considered the cited references.

Applicant's "Response to Restriction/Election Requirement" filed November 12, 2004 has been received and entered into the application.

Requirement for Restriction/Election

Applicant's election of Group I (claims 1-2, 5-7 and 9-11), drawn to a method for modulating the metabolism of fluoroquinolone resistant pathogenic bacteria with a gemifloxacin compound or antibacterially effective derivatives thereof, **with traverse** in the reply filed November 12, 2004 has been acknowledged.

Upon further consideration of the claims and Applicant's remarks at page 2 of the reply filed November 12, 2004, the Examiner has **withdrawn** the requirement for restriction as set forth at pages 3-4 of the Office Action dated October 8, 2004. In light of Applicant's arguments

and further review of the subject matter and the prior art, examination of all of the claims does not place an undue burden on the Examiner.

Examination of the full scope of claims 1-11 has been performed and such claims are herein acted on the merits.

Objection to the Claims

Applicant is advised that should claim 2 be found allowable, claims 10 and 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. The Examiner does not consider the claim limitation "said fluoroquinolone resistant pathogenic bacteria" in claim 2 to differ in scope from the claim limitation "said bacteria" in claim 10 or 11. See MPEP § 706.03(k).

Objections to the Specification

The Examiner has noted the incorporation by reference of PCT Publication WO 98/42705 and European Patent Application 688772 at page 1, line 16 of the disclosure. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the

applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. See 37 C.F.R. 1.57(f).

The disclosure is objected to because the word "topoisomerase" is misspelled at page 2, lines 18, 20, 23 and 26 and at page 4, line 10 of the disclosure.

Applicant is requested to update the priority claim at page 1 before the first line of the disclosure to reflect the current status of United States Patent Application No. 10/323,101, which is now abandoned, and United States Patent Application No. 09/577,732, which is also abandoned. Applicant may wish to consider amending the priority claim to now read:

---This is a continuation of application Serial No. 10/323,101, filed December 18, 2002, now abandoned, which is a continuation of application Serial No. 09/577,732, filed May 23, 2000 ~~(pending)~~, now abandoned, which claimed the benefit of Provisional application Serial No. 60/141,487, filed June 29, 1999. ---

Appropriate correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of bacterial infection, does not reasonably provide enablement for preventing the same. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988). These factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

Factors 1 and 2) The claimed invention is directed to a method for modulating the metabolism of fluoroquinolone resistant pathogenic bacteria comprising contacting the bacteria with an antibacterially effective amount of a gemifloxacin compound or antibacterially effective derivatives thereof (see claim 1, for example), particularly in fluoroquinolone resistant *S. pneumoniae*. Also claimed is a method for treating or preventing a bacterial infection by fluoroquinolone resistant pathogenic bacteria by administering a gemifloxacin compound to a mammal, particularly for the treatment of fluoroquinolone resistant *S. pneumoniae*.

Factor 3) There is a known unpredictability in the art when engaging in the prevention of bacterial infection. While risk factors, such as age, alcoholism, chronic bronchitis, diabetes mellitus, solid tumors of the lung, neutropenia or smoking, for example, are acknowledged in the art to predispose a patient to the development of pneumonia as results from *S. pneumoniae* (see Cecil's Textbook of Medicine, p.1604, Table 319-2), the presence of any one or more of these

risk factors does not necessarily guarantee the development of such a condition when exposed to such a bacteria. Although there are efficacious antibiotic therapies, such as macrolides, lincosines, fluoroquinolones, chloramphenicol or rifamycins (see Cecil's, page 1604, column 1, second full paragraph) that can be used for the relatively predictable treatment of patients exhibiting signs of pneumococcal infection, the use of any one or more of these therapies does not necessarily guarantee that the prevention of such a condition will be achieved. In its broadest interpretation, prevention of a bacterial infection can be achieved only if introduction of the bacteria into the host is avoided. Because contraction of bacteria can occur simply by aspirating air-borne secretions laden with the offending bacteria, absolute prevention of bacterial infection cannot be guaranteed because bacteria are ubiquitous. Furthermore, because the presence of such bacteria occurs on a microscopic level, it would pose an impossible burden to locate and detect any possible bacteria in the air in order to thwart the introduction of the bacteria into the host. In addition, the art does not currently recognize any therapeutic modality guaranteed to prevent bacterial infection because the pathogenesis of such a condition is highly complex and still poorly understood.

Factor 4) Applicant has merely disclosed that by administering the claimed active composition in a patient who is suspected of having, or is at risk of having, an infection with fluoroquinolone resistant pathogenic bacteria, one may prevent the occurrence of such a condition in a patient. Based on the discussion in Section 3 above, however, such disclosure clearly is not adequate direction or guidance as to how the proposed active agent(s) could be employed to accomplish the prevention of bacterial infection in a predictable manner.

Factor 5) The specification at pages 4-5, for example, discloses that use of the presently

claimed active gemifloxacin compound demonstrates substantial activity in *S. pneumoniae* exhibiting resistance to other fluoroquinolones, such as ciprofloxacin. Although Applicant discloses that prevention may be achieved, in the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing bacterial infection or how a patient could be kept from ever developing this condition. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agent for the prevention of such a condition.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, which recognizes particular conventional therapies, such as macrolides, lincosines, fluoroquinolones, chloramphenicol or rifamycins (see Cecil's, page 1604, column 1, second full paragraph) that can be used for the relatively predictable treatment of patients exhibiting signs of pneumococcal infection, for example, the Office would require appropriate disclosure to support the contention that the use of the claim specified active composition could actually prevent bacterial infection by simply administering, by any method, an amount of the claimed active composition, especially in light of the fact that the present specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing such a condition using the claimed active composition.

Factor 6) The burden of enabling the prevention of bacterial infection is much greater than that of enabling the treatment of the same condition. Since the present specification would not enable the skilled artisan to prevent bacterial infection, a clear burden of undue experimentation would be placed upon the skilled artisan in order to practice this aspect of the

invention.

Factor 7) Conventional therapies used to treat a pneumococcal infection, for example, such as macrolides, lincosines, fluoroquinolones, chloramphenicol or rifamycins (see Cecil's, page 1604, column 1, second full paragraph), are well known in the art for treating or reducing the risk of developing bacterial infection. The use of these conventional therapies in patients known to have a bacterial infection is well known in the art, but is not recognized to guarantee absolute prevention of such a condition (see Section 3, above). Furthermore, it is more difficult to prevent the development of bacterial infection than it is to simply treat the condition, since it is recognized in the art that there is no known therapeutic modality that is capable of preventing the introduction of bacteria into a host.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most conditions, especially those having etiologies and pathophysiological manifestations that are as complex as infection, the specification is viewed as lacking an adequate written description of how bacterial infection may be actually prevented.

Factor 8) In view of the discussion of each of the preceding seven factors, the level of skill in this art is high and is at least that of a medical doctor with several years of experience in the art.

Summary

As the cited art and discussion of the above 8 factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that the prevention of bacterial infection could be achieved. In order to

actually achieve prevention of this condition, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. §112, first paragraph. Given that the art fails to recognize and Applicant has failed to demonstrate that bacterial infection could actually be prevented, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 3-4 and 8 are deemed properly rejected.

Suggestion for Overcoming the Rejection

In order to overcome the present rejection, Applicant may wish to consider amending claim 3 in the following manner:

---3. A method of treating ~~or preventing~~ a bacterial infection by fluoroquinolone resistant pathogenic bacteria comprising the step of administering an antibacterially effective amount of a composition comprising a gemifloxacin compound to a mammal suspected of having or being at risk of having an infection with fluoroquinolone resistant pathogenic bacteria.---

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The term "derivatives" in the phrase "a gemifloxacin compound or antibacterially effective derivatives thereof" of present claims 1-2, 5-7 and 9-10 is a relative term that renders the claims indefinite. In particular, "derivatives" does not

particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant. Applicant has failed to provide any specific definition for this term in the present specification. Lacking a clear meaning of the term "derivative", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP §2111.01). Here, the disclosure lacks a definition for the term "derivative"' and does not set forth in a reasonably clear, deliberate or precise manner what other compounds may be considered antibacterially effective gemifloxacin derivatives. That is, there is no limiting definition provided for this term. For example, it is unclear whether Applicant would consider other fluoroquinolone compounds, such as ciprofloxacin or ofloxacin, to be within the scope of the term "antibacterially effective derivatives". Thus, the identity of those compounds that are included or excluded by the "antibacterially effective derivatives" is open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C.

§112, second paragraph.

Rejection of claims 1-2, 5-7 and 9-10 under 35 U.S.C. 112, second paragraph is deemed proper.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 5-6 and 10-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Drugline's Molecule of the Month (Drug News and Perspectives, 11(8), p.505; October 1998).

Drugline teaches that SB-625805 (also knows as gemifloxacin mesylate; see Applicant's acknowledgement at page 1, line 14) demonstrates potent inhibition against resistant pathogens, particularly quinolone-resistant strains of *S. pneumoniae*, where the minimum inhibitory concentration for 90% inhibition is 0.5 μg/ml (see Drugline, p.505, col.3, lines 3-17; referencing to Kim, M.-Y. et al., Abstract F-093 of the 38th Interscience Conference Antimicrobial Agents and Chemotherapy, 1998). Drugline further discloses that SB-265805 has more specific inhibitory effects against bacterial DNA gyrase than some earlier fluoroquinolones (column 2, last sentence of the first full paragraph).

The Examiner has relied upon the abstract of Kim et al. (Abstract F-093 of the 38th Interscience Conference Antimicrobial Agents and Chemotherapy, 1998; cited by Applicant) as referenced by Drugline to define the phrase "quinolone-resistant". Kim et al. discloses,

> "Recently several new quinolones, such as trovafloxacin, grepafloxacin, sparfloxacin and moxifloxacin have become available for clinical and/or investigational use...however, their use may be limited by the increasing incidence of resistance against these agents in strains of *S. pneumoniae*..." (see column 1, "Introduction", first paragraph).

Thus, the Examiner interprets the phrase quinolone-resistant to encompass those strains of *S. pneumoniae* that are resistant to trovafloxacin, grepafloxacin, sparfloxacin or moxifloxacin. Moreover, although the abstract of Kim et al. refers to such compounds as "quinolones", quinolones such as trovafloxacin, grepafloxacin, sparfloxacin or moxifloxacin were known in the art to be synonymous with the term fluoroquinolones (see Piddock et al., "Activities of New Fluoroquinolones against Fluoroquinolone-Resistant Pathogens of the Lower Respiratory Tract", see Table 1 at page 2957; relied upon by the Examiner to show that the quinolone compounds taught by Kim et al. are the same as fluoroquinolones). In concurrence with MPEP §2131.01, it is proper to rely on another reference for a rejection under 35 U.S.C. §102, provided that the additional reference is relied upon in order to explain the meaning of a term used in the primary reference.

While the Examiner acknowledges that the Drugline reference does not expressly disclose that SB-265805 is capable of modulating the metabolism of fluoroquinolone resistant pathogenic bacteria, the reference expressly discloses the inhibitory effects of SB-265805 against bacterial DNA gyrase. Thus, modulation of the metabolism and, further, the inhibition of the growth of or the killing of the bacteria would have been an obvious property of the active agent. Drug Actions: Basic Principles and Therapeutic Aspects has been relied upon to show that inhibition of DNA gyrase interferes with the sealing of DNA strands, which causes a rapid breakdown in the metabolism of the susceptible bacteria (see page 541, col.1, first paragraph). Furthermore, the bactericidal (i.e., killing of the bacteria) property of the active agent as recited

in present claim 6 would also have been an obvious property, since interference with the bacterial metabolism would eventually render the cell unable to maintain its normal function and, thus, cause it to die. In concurrence with MPEP §2131.01, it is proper to rely on multiple references for a rejection under 35 U.S.C. §102, provided that the additional references are relied upon in order to show that a characteristic not disclosed by the reference is inherent.

Lastly, the Examiner considers the disclosure of the minimum inhibitory concentration for 90% inhibition (0.5 μg/ml) to meet Applicant's limitation of an "effective amount" (see col.3, lines 3-17).

Rejection of claims 1-2, 5-6 and 10-11 under 35 U.S.C. §102(b) is deemed proper.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drugline's Molecule of the Month (Drug News and Perspectives, 11(8), p.505; October 1998), as applied to claims 1-2, 5-6 and 10-11 for the reasons of record set forth above, and further in view of Kim et al. (Abstract F-093 of the 38th Interscience Conference Antimicrobial Agents and Chemotherapy, 1998; cited by Applicant).

The differences between the Drugline reference and the presently claimed subject matter lie in that the reference does not teach:

(i) a method of modulating the metabolism of fluoroquinolone-resistant pathogenic bacteria in a mammal, particularly a human (see present claims 7 and 9) **or** a method of treating a bacterial infection comprising the administration of a gemifloxacin compound to a mammal, particularly a human (see present claims 3-4 and 8); and

(ii) the particular types of fluoroquinolone resistant pathogenic bacteria as recited in claim 1, for example.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Although the Drugline reference does not expressly disclose the use of the agent SB-265805 in a method of modulating the metabolism of bacteria or a method of treating a bacterial infection, particularly a human, Drugline acknowledges that the active compound (SB-265805)

is being developed for the treatment of community-acquired infections. Moreover, Kim et al. acknowledges the same, stating "SB-265805 is a new fluoroquinolone currently under development for the treatment of community-acquired infections...The enhanced antibacterial activity of SB-265805 against common respiratory tract pathogens suggests great potential for this compound in treating RTIs." (see last paragraph under "Introduction" in column 1 and Conclusions). In light of such, it would have been obvious to the skilled artisan that SB-265805 would be reasonably expected to demonstrate efficacy in treating bacterial infections in humans, particularly those resulting from quinolone-resistant strains of *S. pneumoniae*. It was well known in the art that in vitro testing of bactericidal or bacteriostatic properties of antibacterial compounds were reasonably, if not significantly, suggestive of activity in vivo. Thus, the skilled artisan would have been motivated to use such an agent in the treatment of a bacterial infection caused by fluoroquinolone resistant pathogenic bacteria in a human since the agent had already demonstrated appreciable efficacy in vitro and would have been reasonably expected to demonstrate the same or similar efficacy in vivo.

(ii) While it is acknowledged that Drugline teaches quinolone-resistant strains of S. pneumoniae in general but does not expressly disclose each and every type of resistant strain with the respective mutations as recited in present claim 1 (for example), the Examiner considers the general teaching of the genus of quinolone-resistant strains of *S. pneumoniae* to encompass any and all strains of *S. pneumoniae* known in the art to be quinolone-resistant. Therefore, it would have been apparent to the skilled artisan that those quinolone-resistant strains of *S. pneumoniae* as recited in present claim 1 were well within the scope of the reference and such strains would have been reasonably expected to experience the same or similar inhibitory effects

of the active fluoroquinolone agent SB-265805 as those taught by the reference, absent factual evidence to the contrary.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional

Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-38 of U.S. Patent Application No. 10/262,826.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the copending applications are not considered to be patentably distinct from each other

because the copending claims clearly anticipate the present claims. The present claims require the use of a gemifloxacin compound, or antibacterially effective derivatives thereof, which is clearly anticipated by the copending claims. While the copending claims of U.S. Patent Application No. 10/262,826 recite the use of a gemifloxacin compound in combination with a ciprofloxacin compound, or antibacterially effective derivatives thereof of either or both compounds, the present claims merely require the presence of an antibacterially effective amount of gemifloxacin compound, which is clearly provided for in the copending claims. In addition, the present claims use the word "comprising", which is considered open transitional claim language and allows for the use of other components with the active agent recited in the present claim (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the additional components, such as the use of a ciprofloxacin compound as recited in the copending claims. Furthermore, absent factual evidence to the contrary, the antibacterially effective amounts of the present claims are considered to the same or similar to those of the copending claims, in light of the fact that the host, the active agent and the bacteria of the present claims is the same as that of the copending claims. Therefore, because the present claims clearly provide for the same active agent and the same therapeutic objectives, the Examiner considers the copending claims to anticipate the present claims.

Accordingly, provisional rejection of claims 1-11 of the present application is deemed proper over claims 19-38 of the copending United States Patent Application No. 10/262,826 as claiming obvious and unpatentable variants. The claims are provisionally rejected because the copending claims have not yet been patented.

Non-Provisional

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,803,376 in view of The Merck Manual (Sixteenth Edition, page 94).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the copending applications are not considered to be patentably distinct from each other because the patented claims clearly anticipate the present claims. The present claims require the use of a gemifloxacin compound, or antibacterially effective derivatives thereof, which is clearly anticipated by the patented claims. Furthermore, the pathogenic bacteria recited in the present claims are clearly provided for by the patented claims. While the patented claims of U.S. Patent No. 6,803,376 detail particular regions of parC and gyrA that contain mutations, the species of mutation of parC and gyrA would clearly anticipate the genus of parC and gyrA mutations and, therefore, anticipate the present claims (see MPEP §2131.02). Furthermore, while the present claims particularly recite *S. pneumoniae* while the patented claims (see claims 14-34) recite a pneumococcal pathogenic bacteria, *S. pneumoniae* was known in the art to be a pneumococcal bacteria (see The Merck Manual, p.94, first paragraph under "Bacteriology"). Thus, it would have been obvious to the skilled artisan that the method of the patented claims would have encompassed the method of the present claims.

Accordingly, rejection of claims 1-11 of the present application is deemed proper over claims 1-34 of the U.S. Patent No. 6,803,376 as claiming obvious and unpatentable variants.

Conclusion

Rejection of claims 1-11 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 3, 2005

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